DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JUL 27 2015

Karl Storz Endoscopy
James A. Lee
Senior Regulatory Affairs Specialist
600 Corporate Pointe Drive
Culver City, CA 90230-7600

Re: K021776
Trade/Device Name: KSEA Quadro Switch
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated (Date on orig SE ltr): May 28, 2002
Received (Date on orig SE ltr): May 29, 2002

Dear Mr. Lee,

This letter corrects our substantially equivalent letter of August 15, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K021776

510(k) Number (if known):

Device Name: KSEA Quadro Switch

Indication for Use: The KSEA Quadro Switch, in conjunction with its associated handpiece, functions as a suction/irrigation control switch device to control the rinsing and removal of carbon deposits, blood clots, or excised tissue from operative sites during surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ OR Over-the-Counter Use: _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021776

AUG 15 2002

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS** K021776

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KSEA's knowledge.

**Application**:

Karl Storz Endoscopy – America, Inc.
600 Corporate Pointe Drive
Culver City, CA 90230
(310) 338-8100

**Contact**:

James A. Lee, Ph.D.
Senior Regulatory Affairs Specialist

**Device Identification**:

Common Name:
Suction/Irrigation Switch

Trade Name: (optional)
KSEA Quadro Switch

**Indication**: The KSEA Quadro Switch, in conjunction with its associated handpiece, functions as a suction/irrigation control switch device to control the rinsing and removal of carbon deposits, blood clots, or excised tissue from operative sites during surgical procedures.

**Device Description**: The Quadro Switch is a microprocessor controlled device connected at the interface between a suction/irrigation handpiece and a legally marketed irrigation/suction pump via two separate pieces of silicone irrigation and suction tubing.

**Substantial Equivalence**: The KSEA Quadro Switch is substantially equivalent to the predicate devices since the basic features and intended uses are the similar. The minor differences between the KSEA Quadro Switch and the predicate devices raise no new questions of safety or effectiveness.

Signed: _____

James A. Lee, Ph.D.
Senior Regulatory Affairs Specialist